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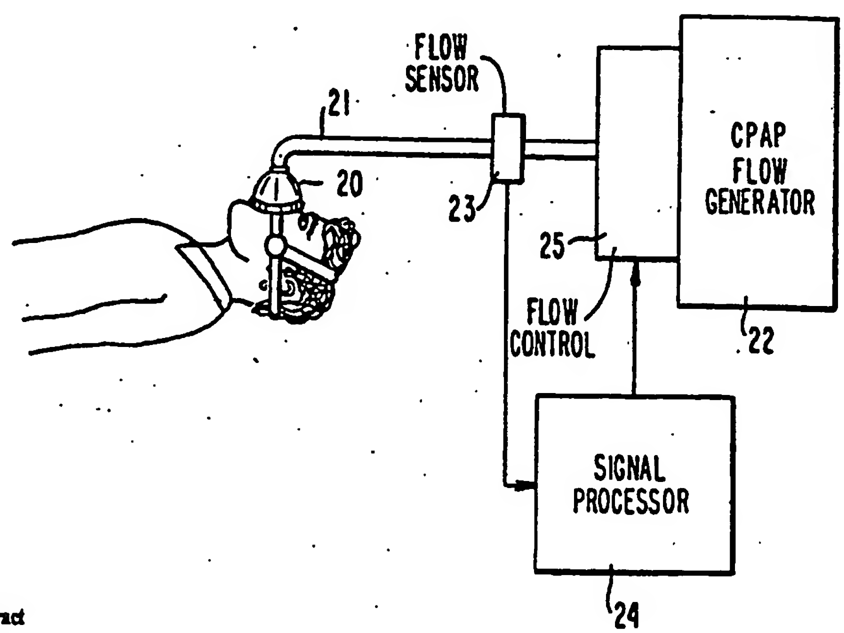
(54) Title: APNEA TREATMENT USING ADJUSTABLE POSITIVE AIRWAY PRESSURE



(57) Abstract

In the treatment of obstructive sleep apnea, a CPAP flow generator (22) is employed to direct air to a nasal mask (20) fitted to a patient. The airflow from the generator is monitored, and the flow and/or pressure is increased through signal processor (24) when the waveform of the air flow exhibits characteristics corresponding to flow limitation. The generator may be controlled to repetitively test for waveform variations, in order to adjust the CPAP flow to the minimum level that does not produce flow limitation.

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APNEA TREATMENT USING ADJUSTABLE POSITIVE AIRWAY PRESSURE

FIELD OF THE INVENTION

This invention relates to a method and apparatus for adjusting the positive airway pressure of a patient to have an optimum (e.g. minimum) value, in the treatment of obstructive sleep apnea,

BACKGROUND OF THE INVENTION

Obstructive sleep apnea syndrome (OSAS) is a well recognized disorder which may affect as much as 1-5% of the adult population. It is one of the most common causes of excessive daytime somnolence, and it is the single most frequent reason for referral to sleep disorder clinics.

The syndrome is characterized by the intermittent obstruction of the upper airway which occurs during sleep. The obstruction results in a spectrum of respiratory disturbances ranging from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring), despite continued respiratory efforts. The morbidity of the syndrome arises from hypoxemia, hypercapnia, bradycardia and sleep disruption associated with the apneas and arousals from sleep. OSAS is most frequent in obese males, and is associated with all conditions in which there is anatomic or functional narrowing of the upper airway, as in heavy snoring.

The pathophysiology of OSAS is not fully worked out. However, it is now well recognized that obstruction of the upper airway during sleep is in part due to the collapsible behavior of the supraglottic segment during the negative intraluminal pressure generated by inspiratory effort. Thus, the human upper airway during sleep behaves as a Starling resistor, which is defined by the property that the flow is limited to a fixed value irrespective of the driving (inspiratory) pressure. Partial or complete airway collapse can then occur associated with the loss of airway tone which is characteristic of the onset of sleep and may be exaggerated in OSAS.

Since 1981, continuous positive airway pressure applied by a tight fitting nasal mask worn during sleep has evolved as the most effective treatment for this disorder, and is now the standard of care. The availability of this non-invasive form of therapy has resulted in extensive publicity for apnea and the appearance of large numbers of patients who previously may have avoided the medical establishment because of the fear of tracheostomy. Increasing the comfort of the system, which is partially determined by minimizing the necessary nasal pressure, has been a major goal of research aimed at improving patient compliance with therapy. Various systems for the treatment of obstructive sleep apnea are disclosed, for example, in "Reversal of Obstructive Sleep Apnea by Continuous Positive Airway Pressure Applied Through The Nares", Sullivan et al, Lancet, 1981, 1:862-865; and "Reversal Of The 'Pickwickian Syndrome' By Long-Term Use of Nocturnal Nasal-Airway Pressure"; Rapaport et al, New England Journal of Medicine, October 7, 1982.

The article "Induction of upper airway occlusion in sleeping individuals with subatmospheric nasal pressure", Schwartz et al, Journal of Applied Physiology, 1988, 64, pp 535-542, also discusses various polysomnographic techniques.

Despite its success, limitations to the use of nasal CPAP exist. These mostly take the form of discomfort from the mask and the nasal pressure required to obliterate the apneas. Systems for minimizing the discomfort from the mask are disclosed, for example, in U.S. Patent Nos. 4,655,213, Rapaport et al, and 5,065,756, Rapaport, as well as in "Therapeutic Options For Obstructive Sleep Apnea", Garay, Respiratory Management, Jul/Aug, 1987, pp 11-15; and "Techniques For Administering Nasal CPAP", Rapaport, Respiratory Management, Jul/Aug. 1987, pp 18-21. Minimizing the necessary pressure remains a goal of the preliminary testing of a patient in the sleep laboratory. However, it has been shown that this pressure varies throughout the night with sleep stage and body position. Furthermore, the therapeutic pressure may both rise or fall with time in patients with changing anatomy (Nasal congestion/polyps), change in weight, changing medication or with alcohol use. Because of this, most sleep laboratories currently prescribe the setting for home use of nasal CPAP pressure based upon the single highest value of pressures needed to obliterate apneas during a night of monitoring in the sleep laboratory. Retesting is often necessary if the patient complains of incomplete resolution of daytime sleepiness, and may reveal a change in the required pressure.

SUMMARY OF THE INVENTION

The invention is therefore directed to a method and apparatus for minimizing the CPAP pressure, in a system for the treatment of obstructive sleep apnea, without causing limitation of airflow to the patient by partial airway obstruction to occur.

Briefly stated an apparatus for the treatment of obstructive sleep apnea is provided, comprising a source of air, and means for directing an air flow from said source to a patient. This part of the system may be of the type

disclosed, for example, in U.S. Patent No. 5,065,756. In accordance with the invention, means are provided for sensing the waveform of said airflow, to detect deviations therein that correspond to flow limitation in the air supplied to the patient. Such deviations may be, for example, deviations from a substantially sinusoidal waveform, flattening, or the presence of plateaus, in the portions of the waveform corresponding to inspiration of the patient. In response to such variations in said airflow, the system of the invention increases the airflow to the patient.

The system may be provided with a program that periodically decreases the airflow in the absence of detection of airflow limitation, and that periodically increases the airflow in the presence of detection of the airflow limitation.

In accordance with the method of the invention, the airflow to the patient is increased in response to the detection of waveform portions corresponding to flow limitations. The increases may be effected periodically. Similarly, the flow may be periodically decreased in the absence of such flow limitation.

BRIEF DESCRIPTION OF THE DRAWING

In order that the invention may be more clearly understood, it will now be disclosed in greater detail with reference to the accompanying drawing, wherein:

Fig. 1 is the waveform of the airflow of a 30 second epoch to a sleeping patient from a CPAP generator, with a CPAP pressure of 10 cm H_2O;

Fig. 2 is the waveform of the airflow of a 30 second epoch to the sleeping patient of Fig. 1, from a CPAP generator, with a CPAP pressure of 8 cm H_2O;

Fig. 3 is the waveform of the airflow of a 30 second epoch to the

sleeping patient of Fig. 1, from a CPAP generator, with a CPAP pressure of 6 cm H_2O;

Fig. 4 is the waveform of the airflow of a 30 second epoch to the sleeping patient of Fig. 1, from a CPAP generator, with a CPAP pressure of 4 cm H_2O;

Fig. 5 is the waveform of the airflow of a 30 second epoch to the sleeping patient of Fig. 1, from a CPAP generator, with a CPAP pressure of 2 cm H_2O;

Fig. 6 is a simplified cross sectional view of a Starling resistor;

Fig. 7 is a simplified block diagram of an experimental setup employing a Starling resistor;

Fig. 8 is a set of waveforms generated by use of the setup of Fig. 7;

Fig. 9 is a simplified block diagram of a system in accordance with the invention;

Fig. 10 is a flow diagram illustrating one technique for adjusting the CPAP pressure, in accordance with the invention.

DETAILED DISCLOSURE OF THE INVENTION

Figs. 1-5 illustrate the waveforms of flow from a CPAP generator, obtained during the testing of a patient, in sleep studies. In these tests, the patient was wearing a CPAP mask connected to an air source, in the manner illustrated in U.S. Patent No. 5,065,765. Each of these tests illustrate an epoch of 30 seconds, with the vertical lines depicting seconds during the tests. Figs. 1-5 depict separate sweeps that were taken from 1 to 2 minutes apart, and with different pressures from the source of air.

Fig. 1 illustrates a "normal" waveform, in this instance with a CPAP pressure of 10 cm H_2O. This pressure was identified as corresponding to obstruction free respiration. It is noted that this waveform, at least in the

inspiration periods, is substantially sinusoidal.

When the CPAP pressure was decreased to 8 cm H_2O, as illustrated in Fig. 2, a partial flattening of the inspiratory flow, at regions 2a, began to occur. This flattening became more definite when the flow was decreased to 6 cm H_2O, as illustrated by the reference numeral 3a in Fig. 3. The flattening becomes even more pronounced, as seen at the regions 4a of Fig. 4, when the flow was reduced to 4 cm. Reductions in the CPAP pressure from the pressure of obstruction free respiration resulted in snoring by the patient. When the flow was reduced to 2 cm H_2O, as illustrated in Fig. 5, there was virtually zero inspiratory flow during the inspiratory effort, as seen at the portions 5a. Shortly after the recording of the waveform of Fig. 5, the patient developed frank apnea and awakened.

The waveforms of Figs. 1-5 illustrate that, as the pressure is lowered, a predictable index of increasing collapsibility of the airway occurs, prior to the occurrence of frank apnea, periodic breathing or arousal.

The waveforms of Figs. 1-5 are consistent with experiments wherein the collapsible segment of the air passage is simulated by a Starling resistor. A Starling resister 10, as illustrated in Fig. 6, is comprised of a rigid external tube 11 supporting an internal collapsible tube 12. Water is introduced into the space between the outer tube 11 and inner tube 12, for example via a tube, from a water column 13 of adjustable height, to enable variation of the external pressure applied to the collapsible tube 12. In this experiment, a commercial CPAP flow generator 14 is coupled to the "distal" end of the Starling resistor 10, and "respiration" is simulated by a sinusoidal pump 15 coupled to the "proximal" or "intrathoracic" end of the resistor 10. A volume reservoir 16 is coupled to the proximal end of the Starling resistor, to provide a capacitive volume that prevents excessive negative pressure from developing

during total system occlusion (apnea).

The flow tracing of Fig. 7 was generated using the system of Fig. 6, with the level of water in the column 13 set between 5 and 15 cm H_2O. The airflow from the CPAP flow generator was started at 14 cm H_2O, then sequentially decreased to 12 cm, 11 cm, 8 cm and 6 cm H_2O, and finally returned to 13 cm H_2O. In this figure, the upper curve shows the waveform of the airflow, the middle curve shows the waveform of the proximal pressure (i.e. at the port of the sinusoidal generator 15, and the lower curve illustrates the CPAP pressure. The gradations at the top of Fig. 7 denote seconds. Fig. 7 thus reflects the large increase in resistance across the Starling resistor, and mimics the increasingly negative intrathoracic pressure routinely seen in patients with an apnea, snoring and any increased airway resistance syndrome..

In accordance with the invention, analysis of waveforms of the flow of air, of the type illustrated in Figs. 1-5, is employed in order to control the flow of air from a CPAP generator, to thereby minimize the flow of air from the generator while still ensuring that flow limitation does not occur.

In one embodiment of the invention, as illustrated in Fig. 8, a CPAP mask 20 is connected via tube 21 to receive air from a CPAP flow generator 22. These elements may be of the type disclosed in U.S. Patent No. 5,065,756, although the invention is not limited thereto, and any conventional CPAP system may alternatively be employed. A conventional flow sensor 23 is coupled to the tube 21, to provide an electric output signal corresponding to the waveform of the airflow in the tube 21. This signal is applied to a signal processor 24, which detects the existence in the waveforms of conditions that indicate flow limitation. The signal processor 24 outputs a signal to a conventional flow control 25 for controlling the pressure applied by the flow generator to the tube 21. It is of course apparent that, depending upon the

type of flow generator 22, the signal processor may directly control the flow generator, instead of controlling a flow control device 25.

One method for adjusting the CPAP pressure in accordance with the invention is illustrated in Fig. 10. After the CPAP mask has been fitted to a patient, and the CPAP generator has been connected to the mask, at step 40 the CPAP pressure is set at a starting pressure. This pressure is a pressure at which flow limitation for the patient does not occur. After a settling period of about 30 seconds, at step 41, the flow signal is analyzed, at step 42.

If it is determined in step 43, that flow limitation has occurred. and the CPAP pressure is less than the maximum allowed as determined at step 44, the CPAP pressure is increased by 0.5 cm H_2O, at step 45, and the procedure jumps back to the settling step 41 for further processing. If, at step 44, the pressure was not less than the maximum allowed CPAP pressure, the program jumps back to the settling step 41 without increasing the CPAP pressure.

If, at step 43, it was determined that a flow limitation was not present, then a determination is made, at step 46, if a predetermined time has elapsed following the last change in the CPAP pressure. The predetermined time may be, for example, two minutes. If the predetermined time has not elapsed, the program jumps back to the settling period of step 41. Otherwise, i.e. if the predetermined minimum time has elapsed, at step 47 it is determined whether or not the CPAP pressure is greater than the minimum allowed pressure. If it is greater than the minimum allowed pressure, then the CPAP pressure is decreased by 0.5 cm H_2O, at step 48, and the program jumps to the settling step 41. Otherwise, the program jumps back to the settling step 41 without decreasing the CPAP pressure.

While the above described example of the method of the invention employed CPAP pressure change steps of 0.5 cm H_2O, it is apparent that the

invention is not limited to steps of this magnitude. In addition, the steps are not necessarily equal throughout the range of adjustment.

In step 43, as above discussed, it was determined if flow limitation was present or not. This step may involve any of a number of waveform analysis procedures. For example, several indices of flow limitation and/or partial airway obstruction which can be used, singly or in combination, include:

1. The derivative of the flow signal equals zero.

2. The second derivative between peaks of the flow signal is zero for a prolonged interval.

3. The ratio of early inspirational flow to midinspirational flow is less than or equal to 1.

The following events, which are not necessarily indications of flow limitation, but do indicate obstructions, in the waveform analysis, may also be employed in the determination of flow limitation:

1. Reduced slope of the line connecting the peak inspiratory flow to the peak expiratory flow.

2. Steep upward or downward stroke (dV/dt) of the flow signal.

3. Ratio of inspiratory flow to expiratory flow over 0.5.

Thus in accordance with the invention, indices of increased inspiratory effort may also be employed which are secondary to airway obstruction, in the face of which flow limitaion becomes more likely. It is evident that analyses of this type may be effected by conventional hardware or software. The invention, however, is not limited to the above specific techniques for determining divergence of the waveform from the normal non-flow limited waveform to a waveform indicating the presence of flow limitation.

While the invention has been disclosed and described with reference to a limited number of embodiments, it will be apparent that variations and

modification may be made therein, and it is therefore intended in the following claims to cover each such variation and modification as falls within the true spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. In an apparatus for the treatment of obstructive sleep apnea, comprising a source of air, and means for directing an air flow from said source to a patient and establishing a pressure at the nose of the patient, the improvement comprising means for sensing the waveform of said airflow, and means responsive to a change in said waveform corresponding to increased upper airway obstruction or flow limitation, in the portions thereof corresponding to inspiration of the patient, for increasing the pressure of air from said source.

2. The apparatus of claim 1 wherein said means responsive to a change in said airflow comprises means for detecting flattening of said waveform in portions thereof corresponding to inspiration periods.

3. The apparatus of claim 1 wherein said means responsive to a change in said airflow comprising means for periodically reducing said airflow by predetermined amounts in the absence of variations in said waveform from a substantially sinusoidal waveform, and means for periodically increasing said airflow in predetermined amounts in the presence of divergence of said portions of said waveform from a substantially sinusoidal shape.

4. In an apparatus for the treatment of obstructive sleep apnea, comprising a source of air, and means for directing an air flow from said source to a patient, the improvement comprising means for sensing the waveform of said airflow, means for detecting plateaus in the portions of said waveform corresponding to inspiration of said patient, and means responsive to detection of said plateaus for increasing the pressure of air from said source.

5. The apparatus of claim 4 further comprising means responsive to the

absence of detection of said plateaus by said detecting means for periodically reducing said airflow, and said means responsive to the detection of said plateaus comprises means for periodically increasing the pressure of air from said source.

6. In an apparatus for the treatment of obstructive sleep apnea, comprising a source of air, and means for directing an air flow from said source to a patient, the improvement comprising means for sensing the waveform of said airflow, means for detecting flattening in the portions of said waveform corresponding to inspiration of said patient, and means responsive to detection of said flattening for increasing the pressure of air from said source.

7. The apparatus of claim 6 further comprising means responsive to the absence of detection of said flattening by said detecting means for periodically reducing said airflow, and said means responsive to the detection of said flattening comprises means for periodically increasing the flow and/or pressure of air from said source.

8. In the method for the treatment of obstructive sleep apnea comprising directing a flow of air to a patient and/or a pressure at the nose of the patient, the improvement comprising monitoring said flow of air to provide waveform signals, and increasing said flow of air and/or pressure in response to the occurrence, in said waveform signals, of signal deviations corresponding to flow limitation in the flow of air to said patient.

9. The method of claim 8 wherein said step of increasing said flow and/or pressure of air comprises increasing said flow and/or pressure of air in response to deviations of said waveform signals in the portions thereof corresponding to inspiration from said patient, from a substantially sinusoidal shape.

10. The method of claim 8 wherein said step of increasing said flow and/or pressure of air comprises increasing said flow and/or pressure of air in response to flattening of said waveform signals in the portions thereof corresponding to inspiration of said patient.

11. The method of claim 8 wherein said step of increasing said flow and/or pressure of air comprises increasing said flow and/or pressure of air in response to the occurrence of plateaus in the portions of said waveform signals corresponding to inspiration of said patient.

12. The method of claim 8 further comprising periodically decreasing said flow and/or pressure of air in the absence of the occurrence, in said waveform signals, of signal deviations corresponding to said flow limitation, and wherein said step of increasing said flow and/or pressure of air comprises periodically increasing said flow and/or pressure of air in response to the presence of waveform signals corresponding to said flow limitation, in order to seek the lowest effective pressure.

FIG. 1

AIRFLOW TO AND FROM CPAP GENERATOR

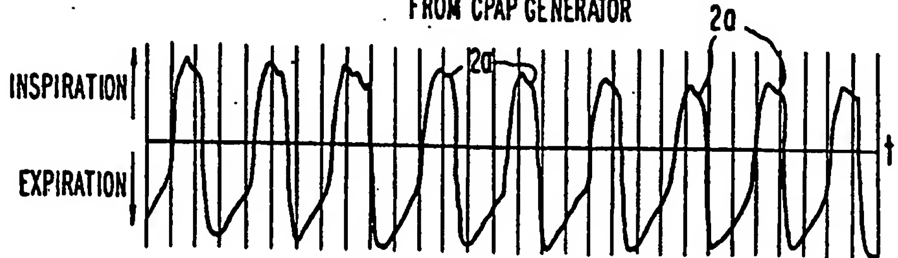

FIG. 2

AIRFLOW TO AND FROM CPAP GENERATOR

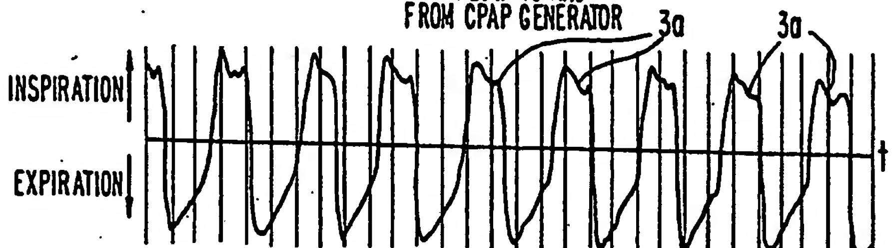

FIG. 3

AIRFLOW TO AND FROM CPAP GENERATOR

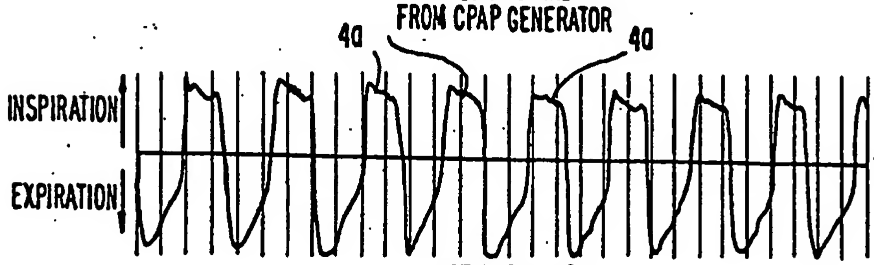

FIG. 4

AIRFLOW TO AND FROM CPAP GENERATOR

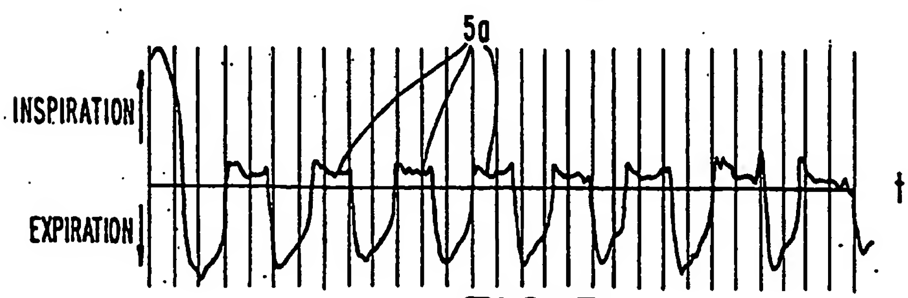

FIG. 5

AIRFLOW TO AND FROM CPAP GENERATOR

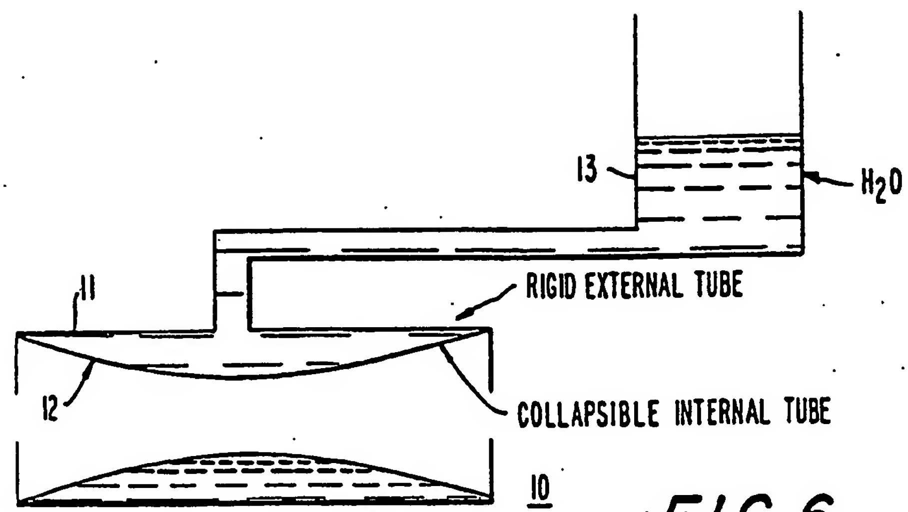
13
H_2O
11
RIGID EXTERNAL TUBE
12
COLLAPSIBLE INTERNAL TUBE
10

FIG. 6

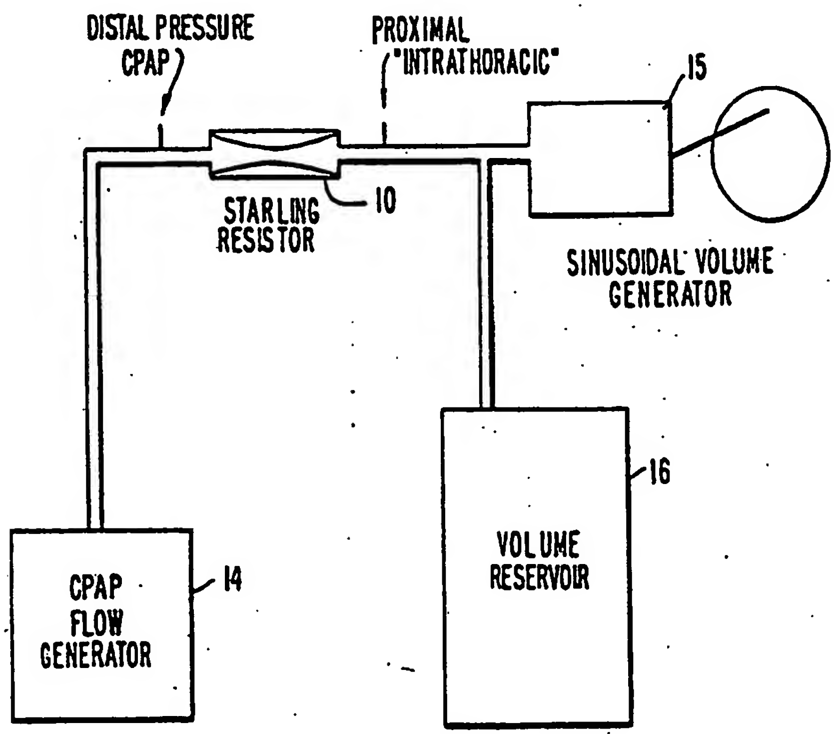
DISTAL PRESSURE
CPAP
PROXIMAL
"INTRATHORACIC"
15
STARLING
RESISTOR
10
SINUSOIDAL VOLUME
GENERATOR
16
VOLUME
RESERVOIR
CPAP
FLOW
GENERATOR
14

FIG. 7

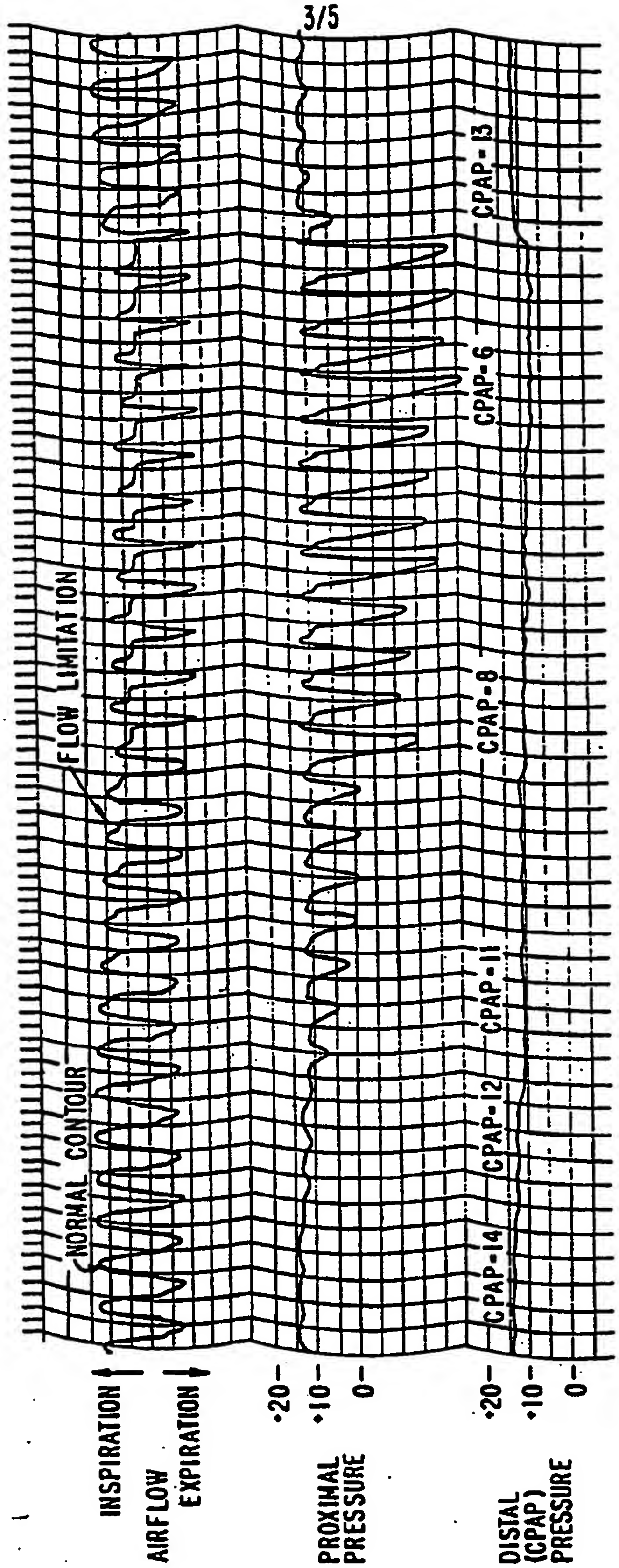
INSPIRATION
AIRFLOW
EXPIRATION
PROXIMAL PRESSURE
DISTAL (CPAP) PRESSURE
20
10
0
20
10
0
NORMAL CONTOUR
FLOW LIMITATION
CPAP-14
CPAP-12
CPAP-11
CPAP-8
CPAP-6
CPAP-13

FIG. 8

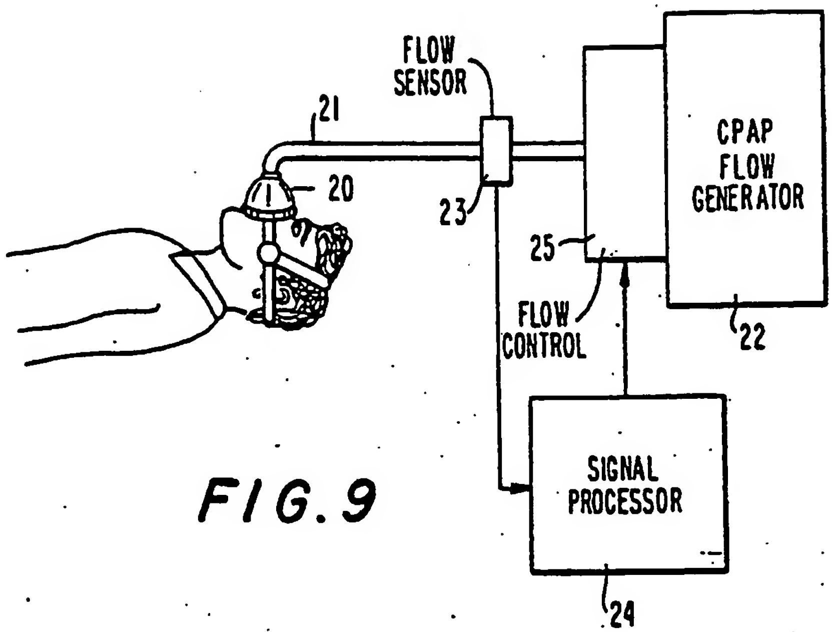
FLOW SENSOR
21
20
23
25
CPAP FLOW GENERATOR
FLOW CONTROL
22
SIGNAL PROCESSOR
24

FIG. 9

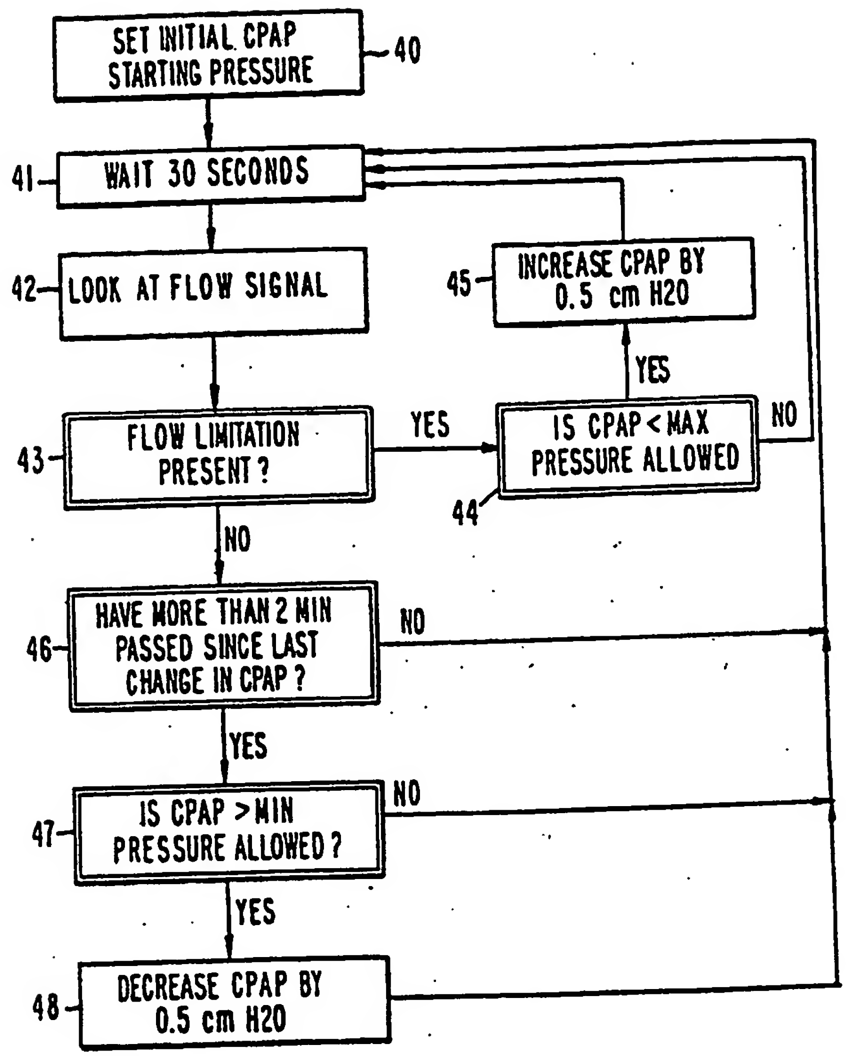
SET INITIAL CPAP STARTING PRESSURE
40
41
WAIT 30 SECONDS
42
LOOK AT FLOW SIGNAL
45
INCREASE CPAP BY 0.5 cm H20
YES
43
FLOW LIMITATION PRESENT ?
YES
IS CPAP < MAX PRESSURE ALLOWED
NO
44
NO
46
HAVE MORE THAN 2 MIN PASSED SINCE LAST CHANGE IN CPAP ?
NO
YES
47
IS CPAP > MIN PRESSURE ALLOWED ?
NO
YES
48
DECREASE CPAP BY 0.5 cm H20

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/04367

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 16/00
US CL :128/204.23
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/204.18,204.21,204.26,205.18,207.18,716-726.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A, 5,107,831 (Halpern et al.) 28 April 1992 See entire document.	1-12
Y	US,A, 4,940,177 (Anderson et al.) 03 April 1984 See entire document.	1-12
Y	Ventilators: Theory & Application, 1986, Yvon Dupuis, pressure cycling, pp. 107-117.	1-12
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Date of the actual completion of the international search	Date of mailing of the international search report
11 JUNE 1993	03 AUG 1993

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